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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,443	08/04/2003	Melvin E. Knisley	AMC3779	4689

7590
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09/21/2004

EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,443

Applicant(s)

KNISLEY, MELVIN E.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 12 and 14 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Status of the Claims

Claims 1-7,10-14 are currently pending for action. Claims 8 and 9 were cancelled and claims 12-14 were newly added pursuant amendment filed on 6/11/2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakahira (4429268) in view of Becker (4643733), Chu (5823852) Kredovski (6062251), Eaton (6520989), Hamas (5496370) and Austad (4157085).

Nakahira discloses that nitrile rubber may be used as medical prosthetic material including in the fabrication of artificial breast (see column 5, lines 10-17). Nakahira does not disclose specifics regarding the prosthesis itself. Becker, Kredovski and Chu show two forms of artificial breasts. One form is for implantation into the patient (Becker and Kredovski) and the other form is for external application on the wearer (Chu). (Note the bra of Chu anticipates the encasement limitation as set forth in new claim 14.) Each of Becker, Kredovski and Chu show a breast device having selective inflation

including a housing having a back wall having a peripheral edge, a front wall being attached to and extending along a length of the peripheral edge such that an inner space is defined between the front and back walls. The front wall having a convex shape such that said front wall extends outwardly away from said back wall, the housing having an opening therein. Each of Becker, Kredovski and Chu show a plug being removably extendable into opening; and wherein a fluid may be selectively added into or removed from said housing until said housing has a desired size. Additionally, Kredovski shows a front wall having an aperture extending therein, the aperture being generally centrally located in said front wall, the aperture being positioned within a generally circular depression in an outer surface of the front wall. Hamas shows a breast device including a housing having openings formed on the front and/or back portion of the device. While the valve locations of Chu and Becker are not specifically set forth, Hamas teaches that the placement of the valve may be on the front and/or back portion of the device. If not inherent in either of Chu or Becker, to place the valve at locations including the front and/or back portion of the device would have been obvious to one with ordinary skill in the art depending on the selected design parameters in the manufacturing process.

None of Becker, Kredovski or Chu disclose the features of the back and front walls comprising a latex material having a thickness generally between .08 mm and 2.0 mm.

Eaton (external breast prosthesis) and Austad (implantable breast prosthesis) teach a range of wall thickness including values falling within the range as claimed by applicant.

One with ordinary skill in the art would look to what is known in the prior art including features directed to the prosthesis physical characteristics including dimensions such as wall thickness, implant size (eg height, width, length, etc.) and filling valves or ports. Nakahira establishes that artificial breast device may be made from nitrile rubber. The secondary references teach the various physical characteristics that are known in the art including wall thickness, implant size (eg height, width, length, etc.) and filling valves or ports. Applicant has put forth a claim that utilizes a collection of features known in the art. These features include the use of latex to keep the cost of the device low, one way valve positioned in an aperture to prevent leakages from the device, and cloth encasement to offer comfort from the latex. Each feature as claimed has been used in the art prior to applicant's invention for the same reasons as put forth by the applicant. It is the examiner's contention that the combination of the latex, aperture/valve and encasement would have been obvious to one with ordinary skill in the art as known physical characteristics selected by the designer based upon routine experimentations to meet the particular design criteria for the artificial breast device. To make the device with a back wall having a peripheral edge, a front wall being attached to and extending along a length of said peripheral edge such that an inner space is defined between said front and back walls is fairly standard in the art. The front wall having a convex shape such that said front wall extends outwardly away from

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said back wall, too, is fairly standard in the art. The device having a wall forming a housing with an opening therein and wherein a fluid may be selectively added into or removed from said housing until said housing has a desired size is known to be well established in the art. A plug being removably extendable into opening to fill the housing of an external or internal device is clearly taught by Becker and Chu. said back wall and said front wall having a thickness generally between .08 mm and 2.0 mm is clearly taught by either of Austad or Eaton. Finally the use of nitrile latex is disclosed by Nakahira.

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-7,10,11 are allowed.

Information Disclosure Statement

The information disclosure statement filed 8/4/03 includes entry to Strain. There is inadequate information concerning the document number pertaining to Strain. Accordingly, Strain has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information

disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Conclusion

Applicant's arguments with respect to claims 12-14 have been considered but are moot in view of the new ground(s) of rejection.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
MARCH 4, 2004